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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,987	05/25/2006	Zhiwen Zhang	54-001021US	5846

22798 7590 05/02/2008

QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.
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EXAMINER	
LEAVITT, MARIA GOMEZ	

ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
05/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/580,987	ZHANG ET AL.	
	Examiner	Art Unit	
	Maria Leavitt	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05-25-2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-61* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-61 are pending in the application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. §121:

I. Claim 3 drawn to **a cell-based** translation system comprising**a** a cell, an orthogonal aminoacyl-tRNA synthetase (O-RS); and an orthogonal tRNA (O-tRNA); **and a mammalian cell** comprising said composition, classifiable in class 435 subclass 68.1.

II. Claim 4 drawn to **an *in vitro* cell-free based** translation system comprising a cell extract, an orthogonal aminoacyl-tRNA,synthetase (O-RS); and an orthogonal tRNA (O-tRNA);, **and a mammalian cell** comprising said composition, classifiable in class 435 subclass 68.1.

III. Claim 31, drawn to **a polypeptide** comprising an amino acid encoded by an orthogonal aminoacyl-tRNA synthetase (O-RS), classifiable in class 530 subclass 402.

IV. Claims 32 and 33 , drawn to **a polynucleotide sequence** which comprises a tRNA that recognizes a selector codon, classifiable in class 424 subclass 93.2.

V. Claims 34-55, drawn to **a method of incorporating an amino acid or unnatural amino acid into a peptide**, comprising introducing an orthogonal mutant

tryptphanyl-tRNA synthetase (O-muTrpRS) and an O-tRNA into a eukaryotic cell, classifiable in class 514 subclass 44.

Claims 1, 2, 5-30, and 56-61 link(s) inventions I and II. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-30, and 56-61. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I and II are directed to related inventions. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the invention of Group II is directed to an *in vitro* cell-free based translation system comprising a cell lyate system does not require the introduction of polynucleotides or ribonucleotides by transformation, as in the case of a cell-base system claimed in Group I. Therefore, Groups I and II are distinct, each from the other. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the invention of Group III is drawn to a polypeptide, whereas the invention of Group IV is drawn to a nucleic acid. The different inventions are distinct from each other because they are drawn to materially different compositions, having different chemical structures, physical properties and biological functions as the result of comprising either polypeptides or polynucleotides; which have different classifications and require separate searches; they are not obvious variants and deemed patentably distinct for the following reasons: polypeptides/proteins, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it

corresponds to the primary amino acid sequence of the encoded polypeptide. Moreover, because of the degeneracy of the genetic code, different nucleotide sequences can encode the same polypeptide sequence. Moreover, the polynucleotide of Group IV is drawn to a different nucleic acid to the one encoding the polypeptide claimed by Group III. The search of inventions in Groups III and IV together would impose a serious search and examination burden, since the combined search of the different compositions, and methods of amino acid incorporation, for prior art and the consideration of patentability of all claims is not coextensive.

Inventions of Groups I or II and III or IV are directed to related inventions. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the invention of Group III is directed to a polypeptide and the invention of Group IV is drawn to a polynucleotide sequence. In contrast, the compositions of Groups I and II employ translation systems comprising O-RS, O-tRNA, wherein O-RS preferentially aminoacylates with an amino acid or unnatural amino acid. Further, the compositions of Groups I and II include molecules such as tRNAs that are distinct from the polypeptide or polynucleotide of Group III or IV. Therefore; Groups I or II and III or IV are distinct, each from the other. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions of Groups I or II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case a composition comprising a translation system (e.g. a cell), can be used in other methods in addition to a method comprising O-muTrpRS and its use in an eukaryotic cell to preferentially aminoacylate a natural or unnatural amino acid, such as using the eukaryotic cell for a binding assay to antigenic components on its surface or using the cell for expression of antibodies. As such, not only a prior art search has to be conducted for each of the invention, a prior art consideration and/or examination of arts relevant to the claimed invention as a whole would be unduly burdensome to the examiner.

Inventions III or IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the polypeptide of Group III comprising an amino acid encoded by an orthogonal aminoacyl-tRNA synthetase can be chemically synthesized in addition to be synthesized by recombinant DNA technologies. Moreover, the inventions of Groups III or IV and V have separate status in the art, as shown in their different classifications. The search of inventions in Groups III or IV and V together would impose a serious search and examination burden, since the combined search of the different compositions, and methods of amino acid incorporation, for prior art and the consideration of patentability of all claims is not coextensive.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

It is noticed that the examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.1 16; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1 .104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting

rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP 804.01.

Species Restriction:

Should Group I or Group II be elected, the claims of the elected group are generic to a plurality of disclosed patentable distinct species comprising:

1) an orthogonal tryptophanyl-tRNA synthetase (O-TrpRS) or an orthogonal mutant tryptophany-tRNA synthetase (O-muTrpRS), as recited in claims 1 and 56,

The species are independent or distinct because there are **O-RS** having different chemical structures, physical properties, and biological functions. For example, each **O-RS** is capable of separate utility for charging of tRNAs with different amino acids, as an O-muTrpRS may contain mutations at one or more amino acid residues.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1 and 34 are generic.

2) Km or Kcat, as recited in claims 8 and 19

The species are independent or distinct because there are **enzymatic properties** resulting from different chemical structures, physical properties, and biological functions. For example, the Km and Kcat utilize separate measures of enzymatic activity, requiring non-overlapping searches and examination, thus imposing a serious burden on the examiner.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1 and 34 are generic.

3) The four base codon, rare codon, UAG, UAA and UGA, as recited in claims 12, 24, and 33.

The species are independent or distinct because there are **selector codons** having different chemical structures, physical properties, and biological functions, requiring non-overlapping searches and examination, thus imposing a serious burden on the examiner

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1 and 34 are generic.

4) a tryptophan analog or 5-hydroxy-L-tryptophan (5-HTPP), as recited in claims 7, 35 and 61.

The species are independent or distinct because there are **unnatural aminoacids** having different chemical structures, physical properties, and biological functions, requiring non-overlapping searches and examination, thus imposing a serious burden on the examiner.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1 and 34 are generic.

Should Group V be elected, the claims of the elected group are generic to a plurality of disclosed patentable distinct species comprising:

5) a reporter tag or a purification tag, as recited in claim 49.

The species are independent or distinct because there are **protein tags** having different chemical structures, physical properties, and biological functions, requiring non-overlapping searches and examination, thus imposing a serious burden on the examiner.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1 and 34 are generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to

petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also

enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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